REMARKS

I. Status of the Claims

Claims 1-25 and 27-49 are currently pending, with claims 1-24, 28-36 and 42 having been withdrawn from consideration as drawn to non-elected subject matter. Upon entry of this amendment, claims 25 is amended and claim 42 canceled without prejudice or disclaimer. Claim 42 is canceled only because it has been withdrawn as directed to a non-elected invention. New claims 50 and 51 are introduced upon entry of this amendment.

The amendment to claim 25 and new claims 50 and 51 find support, for example at page 13, lines 1-9 and page 17, lines 4-16.

II. Rejection of Claims under 35 U.S.C. 112, First Paragraph

A. Written Description

Claims 25, 27, 37-41 and 43-49 are rejected because the specification is said not to describe the claimed subject matter is such a way as to demonstrate that applicants were in possession of the claimed subject matter at the time the application was filed.

Under the Written Description Guidelines, a claim directed to a genus (e.g., independent claim 25) can satisfy the written description requirement by, for example, disclosing "relevant identifying characteristics" (Fed. Reg., vol. 66, page 106 (January 5, 2001)). Examples of such characteristics are said to include: (i) structures or other chemical or physical properties, (ii) functional characteristics coupled with a known or disclosed correlation between structure and function, or (iii) combinations of such identifying characteristics.

The specification and claims satisfy the written description requirement by disclosing several relevant identifying characteristics. For example, independent claim 25 defines the proteins of the current invention as having greater than 90% sequence identity to SEQ ID NO:2, thus satisfying the structural criterion set forth in (i). The claims and specification further satisfy the criterion of (ii) by defining the currently claimed proteins both structurally and functionally with respect to a disclosed relationship between structure and function. Specifically, the current claims recite that the claimed proteins can bind a chemokine

selected from the group consisting of ELC, SLC, TECK, CTACK and vMIPII (i.e., a functional characteristic) in the absence of test compound and that the claimed proteins having this activity have at least 90% sequence identity to SEQ ID NO:2 (structure) (see, e.g., claim 25 and page 13, lines 1-9; and page 17, lines 4-7). Thus, the specification and claims clearly provide the identifying characteristics necessary to satisfy the written description requirements as set forth in the Written Description Guidelines.

Furthermore, the position taken in the Office Action is contrary to the conclusion reached in Example 14 of the "Synopsis of Application of Written Description Guidelines" (Synopsis)," which provides examples of the type of analysis used by the Office in evaluating compliance with the written description requirement. Example 14 is directly analogous to the current claims. The claim in Example 14 reads as follows:

"A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B."

Because the claim defines the genus in functional terms that are related to a disclosed correlation between structure and function (see Written Description Guideline criteria above), the Synopsis concludes that the disclosure meets the written description requirements with respect to this exemplary claim. Current independent claim 25 is in the same format as this claim (i.e., it too links functional characteristics to structural characteristics) and, as noted above, this relationship is fully supported by the specification (see, e.g., page 13, lines 1-9; and page 17, lines 4-7). So by analogy, current claim 25 satisfies the written description requirements for the same reasons as the exemplary claim presented in Example 14 of the Synopsis.

For all these reasons it is submitted that the current claims satisfy the written description requirement and that this rejection should thus be withdrawn.

B. Enablement

Claims 25, 27, 37-41 and 43-49 are rejected because undue experimentation of one of ordinary skill would be required to make or use the claimed invention. The Office Action provides primarily two reasons to support this conclusion: (1) the specification is said not to provide adequate guidance to determine which positions of the protein could be altered without having an adverse effect on activity, and (2) the claims are said to be overly broad and, specifically, to lack any structural or functional limitations. For the reasons that follow, Applicants respectfully disagree and address these two assertions in turn.

Contrary to the assertion in the Office Action, the specification provides guidance on what amino acid positions could potentially be altered and with what amino acids without unduly affecting activity. The specification, for instance, teaches that variants can involve conservative substitutions (see, e.g., page 7, line 29 to page 8, line 14). The specification goes on to list specific examples of conservative substitutions (see, e.g., paragraph bridging pages 7 and 9) and cites to the well-known Creighton reference for further guidance on this issue. Moreover, Fig. 2A provides amino acid sequence alignments between CCX CKR and four other chemokine receptors that illustrate conserved and non-conserved regions between these five receptors. Two of these receptors have binding profiles that overlap with CCX CKR. CCR9, for example, binds TECK and CCR7 binds SLC and ELK (see, e.g., page 33, lines 6-27). Thus, those of ordinary skill in the art would know that one logical approach for making variants of SEQ ID NO:2 that have the binding activity recited in the current claims would be to make alterations in non-conserved regions, as such regions appear to tolerate differences. The examples in the specification also describe the use of certain fusion proteins in screening methods related to the currently claimed methods. Finally, the screening methods that are described in the specification (see, e.g., page 17 line 16 to page 18, line 16) can be utilized to rapidly screen variants that have been formed to identify particular variants that have the desired activity.

In response to the second concern that the claims fail to recite any structural or functional limitations, it is noted that the claims as amended do include a structural aspect (e.g., the variant has greater than 90% sequence identity with SEQ ID NO:2) and a functional aspect

(e.g., ability to bind a chemokine recited in the claims). Thus, the claims are not unduly broad in view of these two requirements.

In view of the foregoing two concerns, the Office Action concludes at page 7 that a "large quantity of experimentation" would be necessary to practice the invention. It is noted, however, that considerable (or a "large quantity") of experimentation to practice an invention does not necessarily equal "undue experimentation." As stated in *In re Wands*, 8 USPQ2d 1400, 858 F.2d 731, 737 (Fed. Cir. 1988):

> [E]xperimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art...*The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.* (emphasis added).

So experimentation is not undue if *either* of two requirements are satisfied: 1) the experimentation is routine, OR 2) the specification provides reasonable guidance in the direction the experimentation should proceed. As just described, the application provides significant guidance on candidate amino acids that could potentially be altered without adversely affecting activity based on the homology comparisons, as well as providing guidance on appropriate substitutions. Such guidance satisfies criterion 2. If variants need to be screened for the desired activity, such screening would be routine in view of the previously described screening methods, which is in accordance with criterion 1.

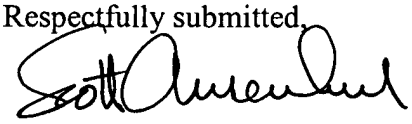
So for all these reasons, it is submitted that the current claims satisfy the enablement requirement. Accordingly, it is requested that this rejection be withdrawn.

III. Rejection of Claims under 35 U.S.C. 102

Claims 25, 27, 37-41 and 46 are rejected as anticipated by U.S. Patent 6,110,695 to Gunn et al. ("Gunn"). In response it is noted that Gunn is not believed to discuss proteins with the sequence of CCX CKR polypeptide having the amino acid sequence as set forth in SEQ ID NO:2, or fragments or variants thereof, wherein the variant has at least 90% amino acid sequence identity with SEQ ID NO:2. As such, Gunn fails to anticipate the currently pending claims.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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